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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/083,476

02/27/2002

Roger N. Piasio

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08/20/2008

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/083,476	<b>Applicant(s)</b> PIASIO ET AL.	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/23/08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 04/23/08 in response to the non-final Office Action mailed 01/24/08.

### **Status of Claims**

- 2) Claim 22 has been amended via the amendment filed 04/23/08.  
Claim 22 is pending.

### **Prior Citation of References**

- 3) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

- 4) The objection to the abstract made in paragraph 6 of the Office Action mailed 04/23/08 is withdrawn in light of Applicants' amendment to the abstract.

### **Objection(s) Maintained**

- 5) The objection to the specification made in paragraph 3 of the Office Action mailed 7/27/04 and maintained in paragraph 8 of the Office Action mailed 12/29/05, paragraph 6 of the Office Action mailed 12/05/06, paragraph 8 of the Office Action mailed 08/27/07 and paragraph 7 of the Office Action mailed 01/24/08, is still maintained for reasons set forth therein and herein below.

Applicants contend that they have amended the specification at page 4 to delete any incorporation by reference language regarding U.S. serial no. 09/518,165 via their amendment/response filed 05/27/07. Applicants argue that there is no incorporation by reference to a U.S. patent application which itself incorporates essential material by reference, and that the objection has been overcome.

Applicants' arguments have been carefully considered, but are not persuasive. Contrary to Applicants' assertion, the amendment to the specification filed in May, 2007 deleted the incorporation by reference language that was associated with the US patent application 09/399,710,

but not of the US application no. 09/518,165. For Applicants' convenience, that amendment as submitted by Applicants is reproduced below:

Please amend the first full paragraph on page 4 as follows:

The NOW® bioassay is described and claimed in co-pending, commonly assigned U.S. Patent Application Serial No. 09/399,710 filed September 16, 1999, ~~which is incorporated herein by reference~~ and also its parent application Serial No. 09/156,486 filed September 18, 1998 and now abandoned.

As set forth previously, the instant specification continue to recite and refer to the previously co-pending and now abandoned application, 09/518,165, for disclosure that is essential material to the instant invention. The now abandoned application 09/518,165 that is recited repeatedly in the instant specification, itself incorporates essential material by reference to other co-pending applications, such as, 09/139,720; 09/458,988 etc. The objection stands.

### **Rejection(s) Maintained**

**6)** The rejection of claim 22 made in paragraph 11 of the Office Action mailed 01/24/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is maintained for part of the reasons set forth therein and herein below.

Claim 22, as amended, continues to include the step of flowing the urine sample long the bibulous test strip before the step of immobilizing tagged antibodies capable of binding the C-polysaccharide antigen, for which there appears to be no support in the specification. The description in paragraph bridging pages 8 and 9 of the specification is limited to applying a sample specifically to 'a sample receiving zone' of a bibulous test strip and then allowing to flow of the sample from the sample receiving zone. The description therein is also limited to a 'lateral flow' of the sample and tagged 'purified' antibodies after a deposit of the tagged purified antibody immediately ahead of the 'sample receiving zone' of the bibulous strip. The rejection stands.

### **Rejection(s) Withdrawn**

**7)** The rejection of claim 22 made in paragraph 17 of the Office Action mailed 08/27/07 and maintained in paragraph 10 of the Office Action mailed 01/24/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn. A new rejection is set forth below to address the claim as amended.

**8)** The rejection of claim 22 made in paragraphs 12(a), 12(b), 12(d), 12(e) and 12(f) of the Office Action mailed 01/24/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is

withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claim 22 made in paragraph 12(c) of the Office Action mailed 01/24/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim. A new rejection is set forth below to address the claim 12 amended.

### **New Rejection(s) Necessitated by Applicants' Amendment**

#### **Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)**

10) Claim 22, as amended, is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 22, as amended, includes the limitations: mobilizing 'tagged antibodies' capable of binding the C-polysaccharide antigen of *Streptococcus pneumoniae*, the tagged 'antibodies' having been present on the bibulous test strip .... The limitation 'tagged antibodies' encompasses unpurified, non-isolated antibodies, and isolated antibodies that are capable of binding the C-polysaccharide antigen of *Streptococcus pneumoniae* non-specifically or via cross-reaction. The limitation 'mobilizing' encompasses mobilization of unpurified said tagged antibodies anywhere along the bibulous test strip. However, there is no descriptive support for a method of such scope. Lines 2-4 of page 9 of the specification describe the following:

strip has a sample receiving zone at one end, a deposit of tagged **purified** antibody conjugate located immediately ahead of the sample receiving zone, which deposit is rendered flowable by contact with liquid sample, a region through which sample and tagged purified antibodies flow

This part of the specification thus describes the bibulous test strip to be having a sample receiving zone at one end, a deposit of --purified-- tagged antibody conjugate located immediately ahead of the sample zone, which deposit is rendered flowable by contact with liquid sample. Page 11 of the specification as amended via the amendment filed 10/27/2004 specifically describes the necessity for using antibodies that had been 'purified and rendered antigen-specific':

In all of these examples, test strips were prepared as described in earlier filed, copending Serial No. Application 09/397,110 ~~09/399,710~~ using **antibodies to *Streptococcus pneumoniae* that had been purified and rendered antigen-specific** as described in that application. In all of these tests, the capture lines were striped on the test strip membranes by passing each of them under the delivery tip of a precision pump system at a rate of 0.5 ml. per 6 mm of membrane.

A method as claimed which uses unpurified tagged antibodies capable of binding the C-polysaccharide antigen of *Streptococcus pneumoniae* is simply not supported in the specification as originally filed.

Claim 22, as amended, further includes the new limitation: allowing the binding ‘of a conjugate’ to ‘scrub antibodies’ specific for the conjugates, ‘the scrub antibodies’ immobilized in at least one scrub line along the bibulous test strip. There is no descriptive support in the originally filed specification for ‘scrub antibodies’. Because the limitation ‘a conjugate’ in lines 13, 16 and 21 lacks antecedent basis, it encompasses a generic conjugate of unspecified composition, which is not supported in the specification. Therefore, the above-identified limitations in the amended claim and the current scope of the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C § 112, Second Paragraph**

**11)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**12)** Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 22, as amended, is vague and indefinite in the limitation: ‘scrub antibodies’ (lines 13 and 14), because it is unclear what these antibodies are. The specification does not contain a definition of ‘scrub antibodies’. Furthermore, the metes and bounds of the limitations in the amended claim: ‘scrub antibodies specific for the conjugates’ (see lines 13 and 14) and ‘capture antibodies specific for the conjugates’ (see lines 19 and 20) is not clear because how these antibodies differ from each other in terms of scope is unclear.

(b) Claim 22, as amended, is indefinite and appears to lack antecedent basis in the limitations: 'a conjugate' (see lines 13, 16 and 21). The composition of this conjugate is not clear. Is this 'a conjugate' different from the earlier recited 'the conjugates' that contains the tagged antibodies and the antigen?

### Remarks

**13)** Claim 22 stands rejected.

For clarity, it is suggested that Applicants replace the limitation 'flowing the' all through the amended claim 22, with the limitation --allowing the flow of--.

**14)** Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**15)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**16)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

Application/Control No. 10083476  
Art Unit: 1645  
August 2008

**17)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898, or Robert Mondesi, can be reached at (571)-272-0956.

/S. Devi/  
S. Devi, Ph.D.  
Primary Examiner  
AU 1645

August, 2008